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EXAMINER	
TOTH, KAREN E	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/682,377	**Applicant(s)** DEADWYLER ET AL.	
	Examiner KAREN E. TOTH	**Art Unit** 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2007*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.
  4a) Of the above claim(s) *3,6,21 and 22* is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1,2,4,5,7-20 and 23-39* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  a)☐ All b)☐ Some * c)☐ None of:
    1.☐ Certified copies of the priority documents have been received.
    2.☐ Certified copies of the priority documents have been received in Application No. _____.
    3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
  * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
  Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
  Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

2. Claims 1, 2, 5, 7-10, 11, 13, 15-17, 19, 20, 23-25, and 27-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicolelis (US Patent Application Publication 2003/0083716) in view of DiLorenzo (US Patent 6366813).

Regarding claim 1, Nicolelis discloses a system comprising an interface configured to communicate with electrodes that capture electrical signals that are associated with at least one neuron (elements 12, 14; paragraphs [0052]-[0053]); a waveform processor that is configured to extract neural events having a frequency greater than a particular threshold from the electrical signals (element 16; paragraphs [0057], [0131]-[0134]); and a wireless transmitter configured to wirelessly transmit the extracted neural events (paragraph [0086]). Nicolelis does not disclose the extracted neural events being single neuron action potentials having a frequency greater than 500 Hz.

DiLorenzo teaches a neural monitoring system that is configured to extract single neuron action potentials with waveforms having a frequency exceeding 500 Hz from neural event signals (column 15, lines 41-54; column 29, lines 19-26), in order to remove artifacts and noise from the signal. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Nicolelis and extracted single neuron action potentials with waveform frequencies greater than 500 Hz from the signal, as taught by DiLorenzo, in order to remove artifacts and noise from the captured signal.

Regarding claim 2, Nicolelis further discloses extracting neural events using time/amplitude window discrimination of the signals (paragraph [0173]).

Regarding claim 5, Nicolelis further discloses identifying which neuron is responsible for the neural event with the processor (paragraphs [0052]-[0053]) and wirelessly transmitting that information (paragraph [0086]).

Regarding claims 7 and 37-39, Nicolelis further discloses a wireless receiver for receiving instructions for using a selected category of algorithms for extracting the action potentials exceeding the desired wavelength and providing those algorithms to the waveform processor (paragraph [0086]), where the processor is configured to use the selected category of algorithms to extract the action potentials with waveforms exceeding the user's desired cutoff (paragraph [0057]).

Regarding claim 8, Nicolelis discloses a system comprising an interface configured to communicate with electrodes that capture electrical signals that are associated with at least one neuron (elements 12, 14; paragraphs [0052]-[0053]); a waveform processor that is configured to extract neural events having a frequency greater than a particular threshold from the electrical signals (element 16; paragraphs [0057], [0131]-[0134]); a wireless transmitter configured to wirelessly transmit the extracted neural events (paragraph [0086]); and a wireless receiver that is configured to receive neural stimulation waveforms and provide them to the electrode interface and stimulation electrodes (paragraph [0086]). Nicolelis does not disclose the extracted neural events being single neuron action potentials having a frequency greater than 500 Hz, nor the stimulation electrodes being the same electrodes as the sensing electrodes.

DiLorenzo teaches a neural monitoring system that is configured to extract single neuron action potentials with waveforms having a frequency exceeding 500 Hz from neural event signals (column 15, lines 41-54; column 29, lines 19-26), in order to remove artifacts and noise from the signal. DiLorenzo also teaches using a single electrode array for both sensing and stimulation (column 27, lines 8-10), in order to minimize the amount of implanted components. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Nicolelis and extracted single neuron action potentials with waveform frequencies greater than 500 Hz from the signal, as taught by DiLorenzo, in order to remove artifacts and noise from the captured signal, and used the electrodes for both sensing and stimulation, as taught by DiLorenzo, in order to minimize the number of implanted components.

Regarding claim 9, Nicolelis discloses a system comprising an interface configured to communicate with electrodes that capture electrical signals that are associated with at least one neuron (elements 12, 14; paragraphs [0052]-[0053]); a waveform processor that is configured to extract neural events having a frequency greater than a particular threshold from the electrical signals (element 16; paragraphs [0057], [0131]-[0134]); a wireless transmitter configured to wirelessly transmit the extracted neural events (paragraph [0086]); and that the processor is also configured to generate neural stimulation waveforms (paragraph [0055]) and to provide the neural stimulation waveforms to the neural event interface and electrodes (element 20). Nicolelis does not disclose the extracted neural events being single neuron action potentials having a frequency greater than 500 Hz, nor the stimulation electrodes being the same electrodes as the sensing electrodes.

DiLorenzo teaches a neural monitoring system that is configured to extract single neuron action potentials with waveforms having a frequency exceeding 500 Hz from neural event signals (column 15, lines 41-54; column 29, lines 19-26), in order to remove artifacts and noise from the signal. DiLorenzo also teaches using a single electrode array for both sensing and stimulation (column 27, lines 8-10), in order to minimize the amount of implanted components. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Nicolelis and extracted single neuron action potentials with waveform frequencies greater than 500 Hz from the signal, as taught by DiLorenzo, in order to remove artifacts and noise from the captured signal, and used the electrodes for both sensing and stimulation, as taught by DiLorenzo, in order to minimize the number of implanted components.

Regarding claim 10, Nicolelis further discloses that the interface, the processor, and the transmitter are contained within or on a housing (element 10).

Regarding claim 11, Nicolelis discloses making the system as small as possible in order to make it readily implantable (paragraphs [0178]-[0183]), but does not expressly disclose having the housing be about 5 cubic centimeters in volume. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to constrain the system to about 5 cubic centimeters because the Applicant has not disclosed that volume of about 5 cubic centimeters provides a particular advantage, is for a particular purpose, or solves a stated problem. Moreover, it appears that Nicolelis's system, or Applicant's system, would perform equally well to be implanted and monitor neural events.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Nicolelis such that the housing held about 5 cubic centimeters of volume, because such a modification would have been considered a mere design consideration that fails to patentably distinguish over Nicolelis.

Regarding claim 13, Nicolelis further discloses that the electrical signals associated with at least one neuron are generated by at least one neuron (paragraphs [0052]-[0053]).

Regarding claim 15, Nicolelis further discloses that the electrical signals associated with at least one neuron may be generated by an in vivo subject (paragraphs [0040], [0055]).

Regarding claim 16, Nicolelis further discloses that the electrical signals are generated by at least one neuron (paragraphs [0052]-[0053]) in conjunction with a feedback control interface to a prosthesis or other neural interface (paragraphs [0008], [0055]).

Regarding claim 17, Nicolelis further discloses that the system may comprise a base station (element 24) that is configured to wirelessly receive the neural events and to further process them (paragraphs [0079], [0086]).

Regarding claim 19, Nicolelis discloses a method of detecting neural events comprising capturing electrical signals that are associated with at least one neuron (paragraphs [0008], [0052]-[0053], [0055]); extracting neural events having a frequency greater than a particular threshold from the electrical signals (paragraphs [0008], [0055], [0057], [0131]-[0134]); and wirelessly transmitting the events (paragraph [0086]). Nicolelis does not disclose the extracted neural events being single neuron action potentials with waveforms exceeding 500 Hz in frequency.

DiLorenzo teaches a neural monitoring method comprising extracting single neuron action potentials with waveforms having a frequency exceeding 500 Hz from neural event signals (column 15, lines 41-54; column 29, lines 19-26), in order to remove artifacts and noise from the signal. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Nicolelis and extracted single neuron action potentials with waveform frequencies greater than 500 Hz from the signal, as taught by DiLorenzo, in order to remove artifacts and noise from the captured signal.

Regarding claim 20, Nicolelis further discloses performing time/amplitude window discrimination of the signals to extract events (paragraph [0173]).

Regarding claim 23, Nicolelis further discloses wirelessly receiving instructions for extracting neural events from the electrical signals (paragraph [0086]).

Regarding claim 24, Nicolelis further discloses wirelessly receiving neural stimulation waveforms (paragraph [0086]).

Regarding claim 25, Nicolelis further discloses that the neuron may comprise a neuron (paragraphs [0052]-[0053]).

Regarding claim 27, Nicolelis further discloses that the neuron may be from an in vivo subject (paragraphs [0040], [0055]).

Regarding claim 28, Nicolelis further discloses that the electrical signals are generated by at least one neuron (paragraphs [0052]-[0053]) in conjunction with a feedback control interface to a prosthesis or other neural interface (paragraphs [0008], [0055]).

Regarding claim 29, Nicolelis further discloses wirelessly receiving the neural events and further processing them (paragraphs [0079], [0086]).

Regarding claim 30, Nicolelis discloses a system comprising means for communicating with electrodes that capture electrical signals that are associated with at least one neuron (paragraphs [0008], [0052]-[0053], [0055]); means for extracting neural events having a frequency greater than a particular frequency from the electrical signals (paragraphs [0008], [0055], [0057], [0131]-[0134]); and means for wirelessly transmitting the events (paragraph [0086]). Nicolelis does not disclose the extracted neural events being single neuron action potentials with waveforms exceeding 500 Hz in frequency. DiLorenzo teaches a neural monitoring system that is configured to extract single neuron action potentials with waveforms having a frequency exceeding 500 Hz from neural event signals (column 15, lines 41-54; column 29, lines 19-26), in order to remove artifacts and noise from the signal. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Nicolelis and extracted single neuron action potentials with waveform frequencies greater than 500 Hz from the signal, as taught by DiLorenzo, in order to remove artifacts and noise from the captured signal.

Regarding claims 31, 32, 34, and 35, DiLorenzo further discloses that the extracted waveforms may have frequencies greater than 1000 Hz and less than 10,000 Hz (column 15, lines 41-54; column 29, lines 19-26), since it is well-known in the art that action potential waveforms are generally high-frequency signals. It would have been obvious to one of ordinary skill in the art at the time the invention was made the inventions of Nicolelis in view of DiLorenzo and extracted single neuron action potential waveforms having frequencies between 1000 and 10,000 Hz, since their existence is well-known in the art.

Regarding claims 33 and 36, Nicolelis further discloses capturing electrical signals from a plurality of neurons, and extracting a plurality of individual neural events from the signals (paragraphs [0096], [0105]-[0106]).

3. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nicolelis in view of DiLorenzo, and further in view of Tcheng (US Patent Application Publication 2003/0149457).

Regarding claim 4, Nicolelis discloses all the elements of the current invention, as described above, except for the processor being configured to time-stamp the neural event, and the transmitter being configured to transmit both the events and their associated time-stamps.

Tcheng teaches a system for monitoring neural events comprising identification of neural events with a time stamp (paragraph [0157]), in order to monitor the patient's condition over time. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Nicolelis in view of DiLorenzo with the processor configured to time-stamp the neural events, as taught by Tcheng, and used the transmitter to transmit all the data, including the events and their time-stamps, in order to monitor the patient's condition over time.

4. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nicolelis in view of DiLorenzo, and further in view of Fischell (US Patent 6016449).

Nicolelis in view of DiLorenzo discloses all the elements of the current invention, as described above, except for the processor comprising amplifiers, A/D converters, and a digital signal processor.

Fischell teaches a system for detecting neural events with a waveform processor (element 30) comprising a plurality of amplifiers connected to a neural event electrode interface (elements 32A-32N); a plurality of analog to digital converters, each responsive to an amplifier (elements 33A-33N); and a digital signal processor (element 34) that is responsive to the converters, in order to accurately analyze the recorded signals. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Nicolelis in view of DiLorenzo with a plurality of amplifiers and A/D converters, and a digital signal processor, as taught by Fischell, and used the wireless transmitter to transmit the signals from the digital signal processor, in order to accurately analyze the recorded signals.

5. Claims 14 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicolelis in view of DiLorenzo, and further in view of Gluckman (US Patent 6665562).

Regarding claim 14, Nicolelis in view of DiLorenzo discloses all the elements of the current invention, as described above, except for the neuronal electrical signals originating from an in vitro sample.

Gluckman teaches a system for detecting neural events where neural signals are recorded from in vitro samples (figure 1), in order to ensure the system's accuracy prior to implantation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Nicolelis in view of DiLorenzo and used it to analyze signals from in vitro samples, as taught by Gluckman, in order to ensure the system's accuracy prior to implantation.

Regarding claim 26, Nicolelis in view of DiLorenzo discloses all the elements of the current invention, as described above, except for the neuron comprising an in vitro sample. Gluckman teaches a method of detecting neural events comprising capturing electrical signals from a neuron in an in vitro sample (figure 1), in order to ensure accuracy before implantation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the method of Nicolelis in view of

DiLorenzo to capture electrical signals from an in vitro neuronal sample, as taught by Gluckman, in order to verify the accuracy of event recognition prior to implantation.

6. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nicolelis in view of DiLorenzo, and further in view of Flach (US Patent Application Publication 2001/0023315).

Nicolelis in view of DiLorenzo discloses all the elements of the current invention, as described above, except for the system comprising a plurality of processors and transmitters, and the base station being configured to wirelessly receive neural events transmitted by the plurality of transmitters and to process the received events.

Flach teaches a monitoring system comprising a plurality of electrophysiological sensors, signal processors, and wireless transmitters (elements 102; paragraph [0065]) that are used to monitor patients and send signals to a base station (elements 116, 120) that is configured to wirelessly receive the signals (elements 106) and further process the received events (paragraph [0005]), in order to monitor the status of several patients simultaneously. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Nicolelis in view of DiLorenzo with a plurality of processors and transmitters, and configured the base station to wirelessly receive and process events from all the transmitters, as taught by Flach, in order to monitor several patients simultaneously.

Response to Arguments

7. Applicant's arguments filed 20 November 2007 have been fully considered but they are not persuasive.

Applicant has again argued that Nicolelis would be rendered inoperable if used to extract waveforms greater than 500 Hz. The Examiner must again disagree. Though Nicolelis's bandwidth examples are less than 500 Hz, they are non-limiting examples. There is nothing in Nicolelis precluding using the system, which may be used to identify numerous types of neurological events occurring at a variety of frequencies, to identify those wavelengths exceeding 500 Hz. The particular values in the non-limiting examples are merely proof that the system can operate at a variety of frequencies. Nicolelis leaves open the possibility of using other frequency ranges. DiLorenzo, which, like Nicolelis provides stimulation for control of a neurological disorder, teaches a different frequency range for neurological disorder treatment. As such, DiLorenzo would suggest using a different frequency range in Nicolelis.

Applicant has also argued that DiLorenzo uses separate electrodes for sensing and stimulation. Though both are present in some embodiments, DiLorenzo also uses the stimulation electrodes for both purposes, as cited above.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735